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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,209	09/04/2001	Roland Callens	32232-175096	4220

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[REDACTED] EXAMINER

MAIER, LEIGH C

ART UNIT	PAPER NUMBER
1623	7

DATE MAILED: 11/05/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No. 09/944,209	Applicant(s) Callens	
Examiner Leigh Maier	Art Unit 1623	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on \_\_\_\_\_

2a)  This action is FINAL. 2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1835 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 7, 11, 14, 15, and 17-27 is/are pending in the application

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) 11, 14, 15, and 17 is/are allowed.

6)  Claim(s) 7, 18, and 22-27 is/are rejected.

7)  Claim(s) 19-21 is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. 08/257,292.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- Notice of References Cited (PTO-892)
- Notice of Draftsperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_
- Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- Notice of Informal Patent Application (PTO-152)
- Other: \_\_\_\_\_

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## DETAILED ACTION

### *Status of the Claims*

Claims 7 and 11 have been amended. Claims 12, 13, and 16 have been canceled. Claims 18-27 have been added. Any objection or rejection not expressly repeated has been withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### *Claim Rejections - 35 U.S.C. § 112 - first paragraph*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7, 18, and 22-27 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 7 has been amended to include the limitation "...in which R<sup>3</sup>-N<sup>a</sup>H represents an  $\alpha$ -amino acid. . .and N<sup>a</sup> is a nitrogen atom attached to the  $\alpha$ -carbon of the  $\alpha$ -amino acid." It does not appear that there is support for this limitation in the specification. Applicant points to the paragraph bridging pages 1 and 2 and examples 1 and 2 to support this limitation. However, this passage describes amino acids as broadly defined but does

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not support the limitation of all  $\alpha$ -amino acids. There does appear to be support for the limitation of “essential  $\alpha$ -amino acid[s]” as recited in claim 19 and the species recited in claims 20 and 21. Support is found at page 8, lines 23-24.

***Claim Rejections - 35 U.S.C. § 102***

Claim 7 is rejected under 35 U.S.C. 102(b) as being anticipated by FUNG et al (US 5,032,577), as set forth in the previous Office action. Newly submitted claim 26 is also rejected over this reference.

Applicant’s arguments filed August 20, 2002 have been fully considered but they are not persuasive. Applicant states that there is no suggestion that can be derived from the references that the  $N^{\alpha}$  atom should be connected to the  $\alpha$ -carbon of the  $\alpha$ -amino acid as required by amended claim 7. However, the FUNG compound, set forth in the previous Office action, comprises an “ $R^3$ ” moiety comprising a dipeptide wherein the connecting  $N^{\alpha}$  is the  $N^{\alpha}$  of an  $\alpha$ -amino acid.

Applicant’s amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Allowable Subject Matter***

Claims 11, 14, 15, and 17 are allowed for reasons of record.

Claims 19-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The art of record does not teach or fairly suggest the compounds of the general formula wherein the "R<sup>3</sup>" moiety is the residue of a single  $\alpha$ -amino acid.

***Examiner's hours, phone & fax numbers***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (703) 308-4525. The examiner can normally be reached on Tuesday, Wednesday, or Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (703) 308-4624, may be contacted. The fax phone number for Group 1600, Art Unit 1623 is (703) 308-4556 or 305-3592.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-1235.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.

Leigh C. Maier  
Patent Examiner  
October 31, 2002

  
KATHLEEN K. RONDA  
PRIMARY EXAMINER